

No. 19-___

IN THE
Supreme Court of the United States

CELGENE CORPORATION,
Petitioner,

v.

LAURA A. PETER, DEPUTY UNDER SECRETARY
OF COMMERCE FOR INTELLECTUAL PROPERTY
AND DEPUTY DIRECTOR OF THE U.S.
PATENT AND TRADEMARK OFFICE,
Respondent.

**On Petition For A Writ Of Certiorari
To The United States Court Of Appeals
For The Federal Circuit**

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

When Congress passed the America Invents Act (AIA) in 2011, it created a new administrative proceeding called “*inter partes* review” for reviewing the validity of previously issued patents. See Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 6, 125 Stat. 284, 299-313 (2011). In the same Act, Congress created the Patent Trial and Appeal Board, a new administrative tribunal for conducting *inter partes* review. *Id.* § 7. That Board, now numbering 270-plus “administrative patent judges,” was given the retroactive power to cancel patent rights conferred prior to enactment of the AIA, “even though that procedure was not in place when [those patents] issued.” *Oil States Energy Servs., LLC v. Greene’s Energy Group, LLC*, 138 S. Ct. 1365, 1379 (2018). In just its first four years, the Board invalidated more than 16,600 patent claims, most of which were likely issued before *inter partes* review was enacted.

This case presents a question expressly left open in *Oil States*:

Whether retroactive application of *inter partes* review to patents issued before passage of the America Invents Act violates the Takings Clause of the Fifth Amendment.

**PARTIES TO THE PROCEEDING AND
RULE 29.6 STATEMENT**

Petitioner is Celgene Corporation, a wholly owned subsidiary of Bristol-Myers Squibb Company. Apart from Bristol-Myers Squibb Company, no publicly held corporation owns 10% or more of the stock of Celgene.

Respondent is Laura Peter, the Deputy Director of the United States Patent and Trademark Office. Respondent was an intervenor in the court of appeals.

The Coalition for Affordable Drugs VI, LLC, was the petitioner before the Patent Trial and Appeal Board. The Coalition did not participate in the court of appeals.

STATEMENT OF RELATED CASES

There are no proceedings directly related to this case, other than the proceedings below. These include:

U.S. Court of Appeals for the Federal Circuit:

Celgene Corp. v. Peter, Nos. 18-1167, -1168, -1169, -1171 (Opinion filed July 30, 2019);

U.S. Patent Trial and Appeal Board:

Coalition for Affordable Drugs VI LLC v. Celgene Corp., IPR Nos. 2015-01092, -01096, -01102, -01103 (Final Written Decisions issued Oct. 26, 2016).

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PETITION FOR A WRIT OF CERTIORARI

Celgene Corporation respectfully petitions for a writ of certiorari to review the judgments of the United States Court of Appeals for the Federal Circuit in these cases.

OPINIONS BELOW

The Federal Circuit issued a single opinion resolving three consolidated cases and one companion case. The opinion is published at 931 F.3d 1342 and reprinted in the appendix. Pet. App. 1a-39a. The final written decisions of the Patent Trial and Appeal Board are unpublished, and are printed in the appendix. Pet. App. 40a-200a.

JURISDICTION

The Federal Circuit entered judgment in each case on July 30, 2019. The Federal Circuit denied rehearing in each case on December 9, 2019. Pet. App. 201a-204a. This Court has jurisdiction under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

1. The Takings Clause of the Fifth Amendment to the U.S. Constitution provides, in relevant part:

“... nor shall private property be taken for public use, without just compensation.”

2. Section 6(b) of the Leahy-Smith America Invents Act of 2011, Pub. L. 112-29, 125 Stat. 304, 35 U.S.C. § 311 note, provides:

“[*Inter partes* review] shall take effect upon the expiration of the 1-year period beginning on the date

of the enactment of this Act and shall apply to any patent issued before, on, or after that effective date.”

3. 35 U.S.C. § 6(a) & (c) provide:

Patent Trial and Appeal Board

(a) In General.—There shall be in the Office a Patent Trial and Appeal Board. The Director, the Deputy Director, the Commissioner for Patents, the Commissioner for Trademarks, and the administrative patent judges shall constitute the Patent Trial and Appeal Board. The administrative patent judges shall be persons of competent legal knowledge and scientific ability who are appointed by the Secretary, in consultation with the Director.

(c) 3-Member Panels.— Each appeal, derivation proceeding, post-grant review, and inter partes review shall be heard by at least 3 members of the Patent Trial and Appeal Board, who shall be designated by the Director.

4. 35 U.S.C. § 261 provides, in relevant part:

“Subject to the provisions of this title, patents shall have the attributes of personal property.”

5. 35 U.S.C. § 282(a) provides:

Presumption of validity

(a) In General.— A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid

claim. The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.

STATEMENT

Property rights undergird the U.S. economy. The U.S. legal system reflects this with various measures to protect those rights. One such protection—the principle against unlawful government confiscation—is deeply rooted in our nation’s history and traces back at least 800 years to Magna Carta. *Horne v. Dep’t of Agriculture*, 135 S. Ct. 2419, 2426 (2015). Written into the Constitution as the Takings Clause of the Fifth Amendment, this principle prohibits the government from enacting regulatory laws so burdensome to property rights that they amount to a confiscation. *Pennsylvania Coal v. Mahon*, 260 U.S. 393, 415 (1922).

Patents confer property rights. *Oil States Energy Servs., LLC v. Greene’s Energy Group, LLC*, 138 S. Ct. 1365, 1379 (2018); *James v. Campbell*, 104 U.S. 356, 358 (1881). The Framers underscored this fact in the Constitution by authorizing Congress the power to grant inventors “exclusive right to their ... discoveries,” U.S. Const. art I, § 8, cl. 8, a power the first Congress promptly exercised by enacting the Patent Act of 1790, 1 Stat. 190. And patents are a particularly important property right today, both for innovation and sustained economic growth. Economic research has “amply established a causal link between the development of intellectual property and the growth of our national economy.” F. Scott Kieff, *Property Rights and Property Rules for Commercializing Inventions*, 85 Minn. L. Rev. 697, 699 n.4 (2001).

Inherently attached to property rights—whether they be physical or intangible—are the unusually strong reliance interests they engender. The retroactive application of the America Invents Act (AIA), which unmistakably made revolutionary changes to the Patent Act, upends these reliance interests for patents issued prior to the AIA’s enactment. Those patents, like Celgene’s, vested upon issuance, without any expectation that they would later be subjected to an “efficient” bureaucratic machinery that allows “someone” to “emerg[e] from the woodwork” and argue that “your patent should be canceled [by] a political appointee and his administrative agents.” *Oil States*, 138 S. Ct. at 1380 (Gorsuch, J., dissenting). In Justice Holmes’ words, such government regulation “goes too far.” *Pennsylvania Coal*, 260 U.S. at 415.

1. “The federal patent system ... embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention for a period of years.” *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-51 (1989). The promise of a patent thereby creates powerful incentives to innovate. This ultimately benefits the public who, as a result, obtain new and useful products and methods, learn about (and can build upon) those disclosed inventions, and may freely use these innovations after each patent expires.

The patent bargain therefore creates strong reliance interests. Innovators “rely on the promise of the law” when they invest substantial resources “to bring the invention forth.” *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 731 (2002).

The cost of developing a new pharmaceutical, for example, runs in the hundreds of millions to billions of dollars. See Joseph A. DiMasi et al., *Innovation in the pharmaceutical industry: New estimates of R&D costs*, 47 J. Health Econ. 20-33 (2016). Inventors then rely on the patent laws when they publicly disclose their inventions, thereby giving up any rights to trade secret protection, in exchange for a patent. See *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480-81 (1974) (“[A]dditions to the general store of knowledge are of such importance to the public weal that the Federal Government is willing to pay the high price of [20] years of exclusive use for its disclosure, which ... will stimulate ideas and the eventual development of further significant advances in the art”).

Once a patent issues, reliance interests increase, with patent owners making high-stakes economic decisions based on ownership of the patent. They must decide whether to license a patent, build or outfit facilities to produce the patented technology, or hire employees to make and sell the product, and manage the enterprise. See *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1347 (Fed. Cir. 2010) (en banc) (discussing reliance interests engendered by existing patent law). Indeed, “[m]uch more time and substantially more investment is required to commercialize a product or service embodying an invention than to create the invention in the first place.” FTC, *The Evolving IP Marketplace*, at 41 (March 2011). This Court has noted the importance of those reliance interests, holding that because “inventors ... rely on the promise of the law,” it would eschew changes in patent law that “disrupt the settled expectations of the inventing community.” *Festo*, 535 U.S. at 731, 739.

2. The U.S. Patent and Trademark Office (PTO) issues patents for inventions that meet statutory standards for eligibility and patentability. *See* 35 U.S.C. §§ 101-103. Once issued, a patent remains subject to a limited set of validity challenges in courts and, since 1980, in the PTO. The contours of the administrative procedures for those challenges have changed somewhat over time, but the ones available from 1980 to 2011 were fundamentally different than present-day *inter partes* review (and post-grant review and covered-business-method review). *See generally Oil States*, 138 S. Ct. at 1370-71 (describing the past and current post-issuance review schemes).

a. Before 1980, district-court litigation was the only mechanism for invalidating issued patents. And the hurdles for such invalidation are high: An issued patent is “presumed valid” in district court, 35 U.S.C. § 282(a), a presumption overcome only if the infringement defendant convinces a factfinder with clear and convincing evidence. *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144 (2016).

In 1980, Congress created the first administrative process for post-issuance review in the PTO, *ex parte* reexamination. This procedure, still available today, permits any person to request another patentability review of an already-issued patent. 35 U.S.C. § 302. Only if the PTO determines there is “a substantial new question of patentability” for “any claim of the patent,” can it reexamine the patent. *Id.* §§ 303(a), 304. Reexamination proceeds in the same nonadversarial manner as initial examination, conducted by patent examiners without involvement of the petitioner. *Id.* § 305. The Federal Circuit upheld retroac-

tive *ex parte* reexamination against a variety of constitutional challenges in *Patlex Corp. v. Mossinghoff*, 758 F.2d 594 (Fed. Cir. 1985). But that court treated the Fifth Amendment challenge as one arising under the Due Process Clause, not the Takings Clause, and applied an “arbitrary and capricious” test this Court subsequently rejected as “not a valid method of discerning whether private property has been ‘taken’ for purposes of the Fifth Amendment.” *Lingle v. Chevron USA Inc.*, 544 U.S. 528, 542 (2005). This Court was not asked to review *Patlex*, and the Federal Circuit continues to rely on it, including in this case, Pet. App. 30a, 39a.

In 1999, Congress created a “similar procedure” known as *inter partes* reexamination. *Cuozzo*, 136 S. Ct. at 2137. As with *ex parte* reexamination, this scheme was examinational, not adversarial, and the PTO would determine if the request raised “a substantial new question of patentability affecting any claim of the patent.” 35 U.S.C. § 312(a) (pre-AIA). But under *inter partes* reexamination, the third-party requester could “participate in a limited manner by filing responses and replies” during the proceeding. *Oil States*, 138 S. Ct. at 1371. Congress deliberately made this scheme apply only “to any patent that issues from an original application filed” after that statute’s effective date. Pub. L. No. 106-113, § 4608(a), 113 Stat. 1501A-572 (1999). Likewise, when Congress amended the *inter partes* reexamination statute in 2002 to lower the burden for institution of review and expand appeal rights for patent challengers, it again made the statute prospective only. Pub. L. No. 107-273, §13106(d), 116 Stat. 1900, 1901 (2002) (“The amendments made

by this section apply with respect to any reexamination proceeding commenced on or after the date of enactment of this Act”).

Both types of reexamination were seldom used and therefore provided little risk to issued patents. In fact, patent challengers viewed reexamination as “a much less favored avenue” than litigation. H.R. Rep. No. 112-98, pt. 1, at 45 (2011) (“H.R. Rep.”).

b. After three decades of these seldom-used reexamination schemes, Congress “overhauled the patent system by enacting the America Invents Act,” “phas[ing] out inter partes reexamination.” *Return Mail, Inc. v. USPS*, 139 S. Ct. 1853, 1860 (2019). Congress sought to create a new and more muscular system for canceling what it called “questionable patents” that had been “too easily obtained and are too difficult to challenge.” H.R. Rep., *supra*, at 39.

That new system was embodied in the AIA’s “three new types of post-issuance review proceedings”: *inter partes* review, 35 U.S.C. §§ 311-19, and its parallel schemes called “post-grant review” (for proceedings brought within nine months of a patent’s issuance), *id.* §§ 321-29, and “covered-business-method review” (for proceedings involving that specific type of patent), *id.* § 321 note.

This Court has already recognized that these proceedings are “fundamentally different” than reexamination, *Return Mail*, 139 S. Ct. at 1865, in that, *inter alia*, “[t]he new inter partes review regime looks a good deal more like civil litigation.” *SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1354 (2018); *see also* H.R. Rep.,

supra, at 46-47 (the AIA “converts inter partes reexamination from an examinational to an adjudicative proceeding”).

This transformation from examination to adjudication took form in several specific changes. To begin, *inter partes* review is conducted in a new forum created by the AIA—the Patent Trial and Appeal Board—headed by the politically appointed Director of the PTO and staffed by “administrative patent judges” who review and cancel patents in panels of three. 35 U.S.C. § 6(a), (b)(4), (c). The 270-plus administrative “judges” who currently make up the adjudicative personnel of the Board is roughly 100 “judges” larger than the number of seats within the entire Article III appellate judiciary.¹

Besides the new forum, *inter partes* review differs from reexamination in at least three major ways.

First, for *inter partes* review, the AIA eliminated a patent owner’s unlimited right to amend the patent claims. This is important because of the nature of patent claims and the function of claim amendments.

“The claim is a statutory requirement, prescribed for the very purpose of making the patentee define precisely what his invention is.” *White v. Dunbar*, 119 U.S. 47, 52 (1886); *see* 35 U.S.C. § 112(b) (“The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.”). Like a land survey, a claim defines

¹ Compare USPTO, PTAB Update (Feb. 7, 2019), https://www.uspto.gov/sites/default/files/documents/20190207_PPAC_PTAB_Update.pdf, at p. 4, *with* 28 U.S.C. § 44(a).

the “metes and bounds of the patentee’s invention.” *Thorner v. Sony Computer Entm’t Am. LLC*, 669 F.3d 1362, 1367 (Fed. Cir. 2012).

Claim amendment is an important tool, for patent applicants and holders alike, to tailor claim language to reflect their actual invention over the prior art. See *In re Yamamoto*, 740 F.2d 1569, 1572 (Fed. Cir. 1984) (claim amendment “adjust[s] the scope of claim protection as needed”). The result—amended issued claims—“ensure[s] patentable subject matter remains properly protected.” *Aqua Prods., Inc. v. Matal*, 872 F.3d 1290, 1309 (Fed. Cir. 2017) (en banc) (O’Malley, J.). This enables the inventor to receive “the protection that is warranted, rather than being denied any protection whatsoever.” Greg Reilly, *Amending Patent Claims*, 32 Harv. J.L. & Tech. 1, 20 (2018); see also *Aqua Prods.*, 872 F.3d at 1309, 1312 (claim amendments “preserve the merited benefits of patent claims better than the win-all or lose-all validity contests in district court”); *Yamamoto*, 740 F.2d at 1571 (claim amendments allow an inventor to “obtain protection commensurate with his actual contribution to the art”).

Under *inter partes* reexamination, the patent owner had an unlimited right to amend the patent claims throughout the proceedings, including in response to determinations that the claims, as originally drafted, are not patentable. 35 U.S.C. § 314(a) (pre-AIA). This tool saved many patents from total invalidation during reexamination. Reilly, *supra*, at 15 (“claims are amended in approximately two-thirds of reexaminations, a significantly more common outcome than either complete confirmation or cancellation” of the patent); Gregory Dolin & Irina D. Manta,

Taking Patents, 73 Wash. & Lee L. Rev. 719, 759, 785 (2016) (citing PTO data showing that in *inter partes* reexamination “61% of patents survived only following claim amendments”).

In *inter partes* review, by contrast, claim amendment is highly restricted. To start, a patentee must first seek leave to amend—a right it has only once by statute. It then remains with the Board whether to grant leave to amend, or grant leave for any subsequent motions to amend. 35 U.S.C. § 316(d); *see also In re Cuozzo Speed Techs., LLC*, 793 F.3d 1297, 1301 (Fed. Cir. 2015) (Prost, C.J., dissenting from denial of rehearing *en banc*) (“there is no robust right to amend” in *inter partes* review). And, according to the PTO’s most recent statistics, the Board denies 90% of all motions to amend.²

Moreover, the Board has limited any motions to amend to the outset of the proceeding, “no later than the filing of a patent owner response.” 37 C.F.R. § 42.121(a). This prevents the patentee from amending claims in response to PTO decisions during the proceeding. These restrictions by statute and pursuant to the Board’s expansive powers necessarily curtail the ability of claim amendment to preserve patentable subject matter. In particular, in *inter partes* reexaminations patentees may amend their claims to address the PTO’s determinations of invalidity, but no such right is afforded patentees in *inter partes* reviews.

² USPTO, PTAB Motion to Amend Study, Installment 5, at 7 (Mar. 2019), https://www.uspto.gov/sites/default/files/documents/ptab_%20mta_study_%28installment_5_-_%20update_through_fy2018%29.pdf.

Second, inter partes review gives the patent challenger “broader participation rights” than *inter partes* reexamination. *Cuozzo*, 136 S. Ct. at 2137. That is why *inter partes* review “proceeds before the Board with many of the usual trappings of litigation.” *SAS Inst.*, 138 S. Ct. at 1354. And any “person” other than the patent owner may challenge the validity of a granted patent. *Return Mail*, 139 S. Ct. at 1858. This means that (as happened here) interlopers with no Article III standing may petition for *inter partes* review, obtain that review, and then fully participate as a party throughout the administrative proceeding. The standard for institution is also different: *inter partes* review is not, as with reexamination, limited to “new” unpatentability grounds that were not considered by the examiner who issued the patent. 35 U.S.C. § 314. Moreover, although *inter partes* review has characteristics of litigation, the AIA requires a final decision within one year after institution of review, rushing the adversarial proceedings to a final conclusion. *Id.* § 316(a)(11).

Third, inter partes review applies retroactively to patents granted before the AIA took effect in 2012. AIA § 6(b), 125 Stat. at 304. This was a surprise. As noted, when Congress created *inter partes* reexamination, it deliberately chose not to make that proceeding apply to previously issued patents. *Supra* p.7. But Congress reversed course with the AIA and applied *inter partes* review retroactively. AIA § 6(b), 125 Stat. at 304 (*inter partes* review “shall take effect upon the expiration of the 1-year period beginning on the date of the enactment of this Act and shall apply to any patent issued before, on, or after that effective date.”).

c. “Numerous studies have documented” the staggering consequences of the AIA’s overhaul of post-issuance proceedings. Brian J. Love et al., *Determinants of Patent Quality: Evidence from Inter Partes Review Proceedings*, 90 U. Colo. L. Rev. 67, 104 (2019). According to the PTO’s most recent statistics, 63% of final written decisions in *inter partes* reviews cancel all of the challenged patent claims,³ whereas only 12% of instituted *ex parte* reexaminations,⁴ and only 34% of *inter partes* reexaminations,⁵ resulted in cancellation of all challenged patent claims.⁶

The percentages alone hide the magnitude of the difference between *inter partes* review and *inter partes* reexamination. The raw numbers show these are creatures of a different kind. In about the first decade of *inter partes* reexamination, only 57 reexaminations

³ USPTO, PTAB Statistics, at 10 (Dec. 31, 2019), https://www.uspto.gov/sites/default/files/documents/Trial_Statistics_20191231.pdf.

⁴ USPTO, *Ex Parte* Reexamination Data, at 2 (Sept. 30, 2018) (“All claims canceled” in 12% of cases), https://www.uspto.gov/sites/default/files/documents/ex_parte_historical_stats_roll_up.pdf.

⁵ USPTO, *Inter Partes* Reexamination Data, at 1 (Sept. 30, 2017) (“all claims canceled” in 32% of cases), https://www.uspto.gov/sites/default/files/documents/inter_parte_historical_stats_roll_up.pdf.

⁶ USPTO, PTAB Statistics, at 12 (Mar. 31, 2017), https://www.uspto.gov/sites/default/files/documents/AIA%20Statistics_March2017.pdf.

canceled all claims—about six per year.⁷ In roughly seven years under the AIA, by contrast, 1,867 instituted *inter partes* reviews canceled all claims—about 270 times each year—45 times the rate of *inter partes* reexamination.⁸ In fact, in just its first four years, the Board, armed with its new powers, invalidated more than 16,600 patent claims—a drastically higher rate than its predecessor canceled in reexamination.⁹ All of this has made *inter partes* review a demonstrably attractive machine for patent challengers. In the final fourteen years of *inter partes* reexamination, challengers filed 1,919 reexamination petitions.¹⁰ In the first seven years alone of *inter partes* review, challengers have filed 10,187 petitions.¹¹ Indeed, according to industry experts, the mere *existence* of *inter partes* review has caused the value of all patents—even those never challenged—to fall by two-thirds, costing the U.S. economy in excess of a trillion dollars.¹²

3. Celgene obtained the two patents at issue here a decade or more before Congress enacted the AIA in 2011. The first, U.S. Patent No. 6,045,501 (the '501

⁷ *Inter Partes* Reexamination Data, *supra* n.5, at 8 (showing “all claims canceled” in 57 cases through Sept. 30, 2009).

⁸ PTAB Statistics Dec. 2019, *supra* n.3, at 10 (showing 1867 of final written decisions canceled all instituted claims).

⁹ PTAB Statistics Mar. 2017, *supra* n.6, at 12.

¹⁰ *Inter Partes* Reexamination Data, *supra* n.5, at 1.

¹¹ PTAB Statistics Dec. 2019, *supra* n.3, at 3.

¹² Richard Baker, *America Invents Act Cost the U.S. Economy over \$1 Trillion* (June 8, 2015), <https://patentlyo.com/patent/2015/06/america-invents-trillion.html>.

patent), covers Celgene's System for Thalidomide Education and Prescription Safety (STEPS). STEPS is a system for managing prescriptions that allows Celgene to distribute the teratogenic drug thalidomide more safely. Pet. App. 4a. Teratogenic drugs have important therapeutic uses but can cause serious birth defects if given to pregnant women. Pet. App. 3a. The '501 patent thus covers methods for delivering a teratogenic drug to a patient while preventing fetal exposure.

Celgene filed the application for the '501 patent on August 28, 1998 (before even *inter partes* reexamination was enacted). Pet. App. 241a. During the course of examination, Celgene responded to rejections from the PTO by showing in detail why its claims were novel and non-obvious. Pet. App. 242a-248a. The patent examiner agreed that Celgene's invention was patentable, and the '501 patent issued on April 4, 2000.

The second patent, U.S. Patent No. 6,315,720 (the '720 patent), covers Celgene's Enhanced STEPS. Pet. App. 6a. Enhanced STEPS improves on STEPS by requiring a novel, independent risk assessment before a pharmacist can dispense thalidomide, regardless of what a doctor prescribes. Pet. App. 6a. Celgene filed the application for the '720 patent on October 23, 2000. Pet. App. 249a. During examination, Celgene amended its claims to ensure that the patent met the standards for patentability. Pet. App. 250a-256a. Again, the patent examiner agreed that Celgene's invention was patentable, and the '720 patent issued on November 13, 2001.

4. Nearly fifteen years after the patents issued, the "Coalition for Affordable Drugs," an entity formed

by a hedge-fund manager to challenge patents as part of a stock-shorting strategy, petitioned the Board for *inter partes* review of Celgene's two patents. Pet. App. 2a.¹³ Despite having no kind of dispute with Celgene that could possibly constitute a case or controversy under Article III, the entity was able to use the AIA to challenge the patents. The Board instituted review of both patents. In a series of final decisions, the Board invalidated as obvious all claims of the '501 patent and all but one claim of the '720 patent. Pet. App. 3a.

On appeal, the Coalition did not defend the Board's decisions; instead, the PTO stepped into that role, based on yet another statutory provision unique to the AIA. *See* 35 U.S.C. § 143. The Federal Circuit, conducting deferential APA review of the Board's obviousness determinations, affirmed on the merits. Pet. App. 3a. The court also rejected Celgene's argument that retroactive application of *inter partes* review is an unconstitutional taking. The court concluded that *inter partes* review does not "differ from the pre-AIA review mechanisms significantly enough, substantively or procedurally, to effectuate a taking." Pet. App. 30a.

According to the court, patent owners have known for decades that their patents were subject to invalidation through administrative reexamination. Pet.

¹³ *See* J. Gregory Sidak & Jeremy O. Skog, *Attack of the Shorting Bass: Does the Inter Partes Review Process Enable Petitioners to Earn Abnormal Returns?*, 63 U.C.L.A. L. Rev. Disc. 120, 135-39 (2015); Stephen Foley & David Crow, *Kyle Bass Returns Funds Amid Retreat on Pharma Shorting Campaign*, Fin. Times (Feb. 23, 2016), <https://www.ft.com/content/0ffc05d2-d97e-11e5-98fd-06d75973fe09>.

App. 31a. And the difference between reexamination and *inter partes* review is insufficient, the court said, to upset any settled expectations of patent owners. Pet. App. 33a.

The court relied upon certain general similarities between *inter partes* review and reexamination. Patents are reviewed in each using the same standard of proof (preponderance of the evidence) and on the same substantive grounds (anticipation and obviousness). Pet. App. 33a. Also, at the time Celgene’s patents were subjected to *inter partes* review, the Board used the same standard for claim construction in *inter partes* review and reexamination.¹⁴ Pet. App. 34a. The broad purposes of *inter partes* review and reexamination are also the same—to take “a second look at an earlier administrative grant of a patent.” Pet. App. 35a. Moreover, the court said, “no one has a vested right in any given mode of procedure.” Pet. App. 37a.

Yet, in discussing these broad and general similarities between the proceedings, the court declined to recognize or give effect to their “fundamentally different” natures as recognized by this Court—not just the transformation from examination to adjudication, but the concomitant skyrocketing of patent cancelations, as well as the vast quasi-judicial machinery created and funded by the government to effect those cancelations. And the court left entirely unmentioned a most significant difference: patentees have no right to amend their claims in *inter partes* review, but had an unlimited right to amend in reexamination.

¹⁴ For *inter partes* review, the PTO has since adopted the different standard used in district court litigation. 37 C.F.R. § 42.100 (amended Oct. 11, 2018).

REASONS FOR GRANTING THE PETITION

This Court’s review of the question—a question expressly left open by *Oil States*—is warranted for three reasons. *First*, the question presented is important. The AIA imposes a revolutionary change to the administrative patent system, a change that has eviscerated settled expectations in property rights in every patent in force that issued before the AIA. The effect on property rights, and on the patent system, is staggering. *Second*, retroactive application of *inter partes* review violates the Constitution. Congress’s novel program for canceling patents, along with its sweeping administrative apparatus, results in the taking of private property without compensation. *Third*, this case is a uniquely good vehicle for resolving the question presented. It is the only case in which the Federal Circuit has issued a decision addressing the merits of this issue; without this Court’s review, the Federal Circuit’s unqualified blessing of this administrative patent-canceling machinery will be cemented as national law.

I. THE QUESTION PRESENTED IS IMPORTANT.

This Court has already recognized the importance of resolving questions arising from the congressional overhaul of post-issuance review in the AIA. It has granted five cases on statutory and constitutional questions arising under the AIA; few if any statutes have required more tending by this Court over the first decade of their existence:

- *Cuozzo*, 136 S. Ct. 2131 (addressing statutory questions about appealability from the Board’s decision to institute review and the standard

for construing patent claims during review (§§ 314(d), 316(a)(4));

- *SAS Institute*, 138 S. Ct. 1348 (addressing statutory question whether the Board may grant review on only some claims challenged in a petition (§ 318(a));
- *Oil States*, 138 S. Ct. 1365 (addressing constitutional question whether *inter partes* review by an administrative body violates Article III (§§ 311-319));
- *Return Mail*, 139 S. Ct. 1853 (addressing statutory question whether a government agency is a “person” who may petition for *inter partes* review, *e.g.*, § 311);
- *Dex Media, Inc. v. Click-to-Call Techs., LP*, 139 S. Ct. 2742 (2019) (mem.) (granting certiorari to address (again) statutory question of appealability from the Board’s decision to institute *inter partes* review).

And further, the Federal Circuit is presently grappling with a thorny issue going to the constitutional legitimacy of the appointments of those 270-odd administrative patent “judges.” *Arthrex, Inc. v. Smith & Nephew, Inc.*, 941 F.3d 1320 (Fed. Cir. 2019).

This case presents another important question regarding the legitimate operation of this bureaucratic juggernaut, a question having broad implications for protection of property rights. Indeed, the question presented affects an exceedingly large number of cases, as thousands of *inter partes* reviews continue to retroactively invalidate patents issued before Congress enacted the AIA. Patents issued before the AIA was enacted will remain subject to *inter partes* review

until they expire, no earlier than 2031. *See* 35 U.S.C. § 154(a)(2) (providing for 20-year patent term). The agency’s *en masse* canceling of patents will continue for a decade or more absent this Court’s intervention.

A. The Constitution and this Court’s precedent carefully guard property against retroactive expropriating measures.

Protecting private property has been a central aim of our system of government since the Founding. John Locke, whose ideas greatly influenced the Framers, described the “great and chief end” of government as “the preservation of ... property.” *Second Treatise of Government*, at 62 (Oxford: Blackwell, 1946). Echoing Locke, Alexander Hamilton stated at the Philadelphia Convention that “one great obj. of Govt. is personal protection and security of Property.” 1 *Records of the Federal Convention of 1787*, at 302 (Max Farrand ed., 1911).

The Constitution thus contains various provisions aimed at protecting property rights. These include the Takings Clause of the Fifth Amendment, which mandates: “nor shall private property be taken for public use, without just compensation.” U.S. Const. amend. V. The provision embodies a deeply rooted tradition of protecting private property against uncompensated government intrusion, a tradition that “goes back at least 800 years to Magna Carta.” *Horne*, 135 S. Ct. at 2426 (holding that a regulatory program requiring raisin farmers to set aside “a percentage of the grower’s crop” for the government was a taking).

This Court has emphasized the importance of that tradition. Nearly 100 years ago, the Court held that government regulation that “goes too far” in curtailing

property rights “will be recognized as a taking.” *Pennsylvania Coal*, 260 U.S. at 415. As Justice Holmes explained, “the natural tendency of human nature is to extend [government regulation] more and more until at last private property disappears,” a result that “cannot be accomplished ... under the Constitution.” *Id.* at 412-15 (state law prohibiting certain subsurface coal mining was a taking); *see also, e.g., Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1010-11 (1984) (administrative agency’s disclosure of firm’s trade secret was a taking).

A core purpose of the Takings Clause, this Court has also recognized, is to protect the settled expectations of private property owners against retroactive government action. *See E. Enters. v. Apfel*, 524 U.S. 498, 534 (1998) (plurality) (the Takings Clause “safeguard[s] against retrospective legislation concerning property rights”); *Penn Cent. Transp. Co. v. New York City*, 438 U.S. 104, 105 (1978) (Takings Clause is concerned with regulations that upset “investment-backed expectations”). Yet that is just what is happening here: *inter partes* review retroactively upsets settled expectations over an entire category of property rights.

B. Patents are property protected under the Takings Clause.

Patents are unquestionably protected property rights under the Constitution. An invention patent is a government-issued “right to exclude others from making, using, offering for sale, or selling the invention.” *eBay, Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 392 (2006) (quoting 35 U.S.C. § 154(a)(1)); *see also* 35 U.S.C. § 261 (“patents shall have the attributes of personal property”). Under basic principles of

property law, the “right to exclude” is a hallmark of private property, “universally held to be a fundamental element of the property right.” *Kaiser Aetna v. United States*, 444 U.S. 164, 179-80 (1979).

This Court has therefore explained that “[a] patent confers upon the patentee an exclusive property in the patented invention which cannot be appropriated or used by the government itself, without just compensation, any more than it can appropriate or use without compensation land which has been patented to a private purchaser.” *Horne*, 135 S. Ct. at 2427. This was reaffirmed in *Oil States*, which held that *inter partes* review did not violate Article III because the issuance of a patent involved public rights, but emphasized that the “decision should not be misconstrued as suggesting that patents are not property for purposes of the Due Process Clause or the Takings Clause.” *Oil States*, 138 S. Ct. at 1379; *see also Monsanto*, 467 U.S. at 1003-04 (holding that a “trade secret,” like “other kinds of intangible interests,” is “property for purposes of the Fifth Amendment’s Takings Clause”).

Naturally, the scope of a patent right is qualified by the patent laws. *Oil States*, 138 S. Ct. at 1375 (The Patent Act “qualifies any property rights that a patent owner has in an issued patent, subjecting them to the express provisions of the Patent Act”). But the laws that govern are those existing at the time the patent is issued. Patent rights are not validly subject to new statutory provisions added after the patent is issued that narrow or eliminate those rights. For example, if Congress were to retroactively shorten an issued patent’s term from 20 years to 13, no one would dispute it was a taking.

That was the holding of *McClurg v. Kingsland*, 42 U.S. (1 How.) 202, 206 (1843). There, this Court evaluated the retroactive applicability of an 1836 amendment to the Patent Act. *Id.* The Court held that the amendment could be applied retroactively only if it does “not take away the rights of property in existing patents.” *Id.* A legislative change “can have no effect to impair the right of property then existing in a patentee, or his assignee, according to the well-established principles of this court.” *Id.* Insofar as a statute narrows property rights in the patent, “the patent must ... stand as if” the prior provisions “remained in force.” *Id.*; see *Eldred v. Ashcroft*, 537 U.S. 186, 202-03 (2003) (explaining that *McClurg* applied the 1836 statute retroactively only because it *expanded* the patentee’s rights); see also *Richmond Screw Anchor Co. v. United States*, 275 U.S. 331, 345 (1928) (explaining that interpreting statute to retroactively eliminate right of action for patent infringement would “raise a serious question as to the constitutionality of [the statute] under the Fifth Amendment”).

Thus, while the Patent Act provisions at the time of patent issuance qualify the patent rights, *Oil States*, 138 S. Ct. at 1375, later-added provisions cannot, consistent with the Takings Clause, “impair the right of property then existing in a patentee,” *McClurg*, 42 U.S. (1 How.) at 206.

C. The America Invents Act ushered in a novel regime designed to eliminate existing patents.

Inter partes review does exactly what Congress designed it to do—it broadly extinguishes patents, *supra* p.8, using an “overhauled” system, *Return Mail*, 139 S. Ct. at 1860.

The engine of this new patent-canceling machine is the Patent Trial and Appeal Board. This is no ordinary administrative body, but a vast administrative apparatus comprising 270 administrative patent judges—almost three times as many “judges” than currently authorized for the federal courts of appeals, and nearly half the number of currently authorized district court judgeships in the country. *Supra* p.9 n.1.

The Director of the PTO, a political appointee, governs the Board and wields enormous power. Appointed by the President, the Director holds “broad policy-direction and supervisory authority” over the administrative patent judges. *Arthrex*, 941 F.3d at 1331. The Director possesses unreviewable power to institute review over any patent. *Cuozzo*, 136 S. Ct. at 2139. The Director may then “select which [Board] members, and how many of them, will hear any particular patent challenge.” *Oil States*, 138 S. Ct. at 1381 (Gorsuch, J., dissenting). “If they (somehow) reach a result he does not like, the Director can add more members to the panel—including himself—and order the case reheard.” *Id.*

The overhaul also reached the proceedings themselves; the framework of *inter partes* review is “fundamentally” different from reexamination. *Return Mail*, 139 S. Ct. at 1865. As Congress explained, the AIA “convert[ed] inter partes reexamination from an examinational to an adjudicative proceeding.” H.R. Rep., *supra*, at 46; see *SAS Inst.*, 138 S. Ct. at 1353 (contrasting the “inquisitorial process” of *ex parte* reexamination and the “slightly more adversarial process” of *inter partes* reexamination with the “civil litigation” process of *inter partes* review).

A key difference between “examination” and “adjudicative” proceedings is that *inter partes* reexamination “allowed for continued negotiations between the applicant and the Patent Office” in the form of an unlimited right to amend the patent claims. Dolin, *Taking Patents, supra*, at 784; see *In re Cuozzo Speed Techs., LLC*, 778 F.3d 1271, 1287 (Fed. Cir. 2015) (Newman, J., dissenting) (contrasting the “unfettered opportunity to amend” claims in reexamination proceedings). Amendments allow patent owners to narrow or clarify the substantive scope of their patents in order to save them from total invalidation, just as Celgene did during the examination process for obtaining its ’720 patent. See *Aqua Prods.*, 872 F.3d at 1309 (patentees “use amendment as a tool to narrow claim scope in an effort to ensure its patentable subject matter remains properly protected”). See *supra* pp.9-11.

The examination nature of *inter partes* reexamination allowed the patentee to make amendments at any time, including in response to the examiner’s arguments, in response to the examiner’s rejection of claims, or even on appeal after the examiner reached a final decision. See *In re Varma*, 816 F.3d 1352, 1357 (Fed. Cir. 2016) (reviewing *inter partes* reexamination in which patentee amended claims after the PTO rejected them); 37 C.F.R. § 41.121(a)(2) (“The Board may authorize a party to file a motion to amend or add a claim” in appeal from reexamination). Thus, a patentee could substantially preserve its property by responding to the PTO’s decisions—throughout the proceedings—with amended claims.

In contrast, *inter partes* review allows for “no back-and-forth between the patentee and examiner ...; there is no robust right to amend.” *In re Cuozzo*, 793 F.3d at 1301 (Prost, C.J., dissenting from denial of rehearing *en banc*). In fact, there is no right to amend at all. A patentee must obtain permission from the Board if it seeks to amend its claims, and even then the statute contemplates requesting such permission only once. 35 U.S.C. § 316(d)(1). Moreover, any motion to amend must be made at the outset of the proceeding, “no later than the filing of a patent owner response.” 37 C.F.R. § 42.121(a). This prevents the patentee from amending claims in response to PTO decisions during the proceeding. In any event, the Board virtually never grants these discretionary motions, as its own data show. *See supra* p.11 n.2 (showing that the Board continues to deny 90% of all motions to amend).

The AIA’s severe restrictions on claim amendment are thus a key driver of what makes *inter partes* review more fatal to patents than any previous form of post-issuance review. Reilly, *supra*, at 6 (“the evidence suggests that the AIA post-issuance proceedings have exceeded Congress’s expectations in terms of invalidating issued patents, at least partially due to the near-impossibility of claim amendments”).

The conversion from an examinational to an adjudicative proceeding has gone far to achieve Congress’s goal of quickly eliminating scores of patents. *See Oil States*, 138 S. Ct. at 1380, 1386 (Gorsuch, J., dissenting) (noting “just how efficient” the AIA is at extinguishing patent rights, and explaining that the Constitution protects even against governmental intrusion “take[n] in the name of efficient government”).

As noted above, *supra* pp.13-14, the Board in its first seven years of life received *inter partes* review petitions to cancel patent claims at a rate *ten times* that of its ancestor, the reexamination regime. Furthermore, *inter partes* reviews are “killing” patent claims at a drastically higher rate. *Id.* Indeed, the raw numbers show that the rate of claim cancelation is exponentially higher in *inter partes* review. *Id.* Congress designed it that way. It allowed any “person” to petition for *inter partes* review, 35 U.S.C. § 311(a), and there is no limit on when or how many times any given patent can be subject to *inter partes* review. *See id.* § 311(c). This creates incentives for all manner of abuse. *See* Gregory Dolin, *Dubious Patent Reform*, 56 B.C.L. Rev. 881, 932-47 (2015) (discussing serial attempts at invalidation, stock-shorting schemes, and schemes by third parties who threaten to petition for *inter partes* review unless the patentee makes a “pay-off”).

The broader economic effect of this new system is dramatic. The Board has not only eliminated thousands of issued patents, but the threat of *inter partes* review has devalued all existing patents—even those never challenged. The mere *in terrorem* effect of the Board’s patent-canceling machinery hangs over every patent until it expires. Based on patent-sales data, one industry expert reported that the value of all patents dropped by two-thirds after creation of *inter partes* review. Baker, *supra* n.12. According to this estimate, the AIA “cost the economy about \$1.37 Trillion, or an amount equal to about 7% of the U.S. GDP.” *Id.*

Others have similarly explained that *inter partes* review “is creating unnecessary costs for inventors

and companies, and thus it is harming the innovation economy far beyond the harm of the bad patents it was created to remedy.¹⁵ Still others have noted the AIA’s “dramatic effect on the value of intellectual property assets and the corresponding incentives (or disincentives) to allocate capital to innovation.”¹⁶

All of this is troubling. As Justice Breyer queried at oral argument in *Oil States*, “suppose that [a] patent has been in existence without anybody reexamining it for 10 years and, moreover, the company’s invested \$40 billion in developing it. And then suddenly somebody comes in and says: ‘Oh, oh, ... we want it reexamined.’ ... Now, that seems perhaps that it would be a problem.” Transcript of Oral Argument at 29-30, *Oil States*, 138 S. Ct. 1365. It is.

A statute having such demonstrably staggering effects on the Nation’s innovation economy is indisputably important. Such core issues arising under the AIA warrant this Court’s review, as this Court has repeatedly recognized. See *Cuozzo*, 136 S. Ct. 2131; *SAS Inst.*, 138 S. Ct. 1348; *Oil States Energy Servs.*, 138 S.

¹⁵ Alden Abbott et al., *Crippling the Innovation Economy: Regulatory Overreach at the Patent Office*, Regulatory Transparency Project (Aug. 2017), <https://regproject.org/paper/crippling-innovation-economy-regulatory-overreach-patent-office>.

¹⁶ Ashley Keller, *The PTAB’s dramatic effect on patent value and corresponding disincentives to capital allocation*, IP Watchdog (Sept. 15, 2017), <https://www.ipwatchdog.com/2017/09/15/ptabs-dramatic-effect-patent-value-disincentives-capital-allocation/id=87959/>.

Ct. 1365; *Return Mail*, 139 S. Ct. 1853; *Dex Media*, 139 S. Ct. 2742.

II. RETROACTIVE APPLICATION OF *INTER PARTES* REVIEW VIOLATES THE TAKINGS CLAUSE.

Retroactive application of the AIA has serious constitutional consequences. A regulatory program that destroys all economic value in property is a taking. *Lucas v. South Carolina Coastal Council*, 505 U.S. 1003, 1015 (1992). So too is a regulatory program that goes too far in upsetting investment-backed expectations in property rights. *Penn Cent.*, 438 U.S. at 105. Both tests are met here, and the Federal Circuit was wrong to conclude otherwise. This Court's review of this issue is needed.

A. Retroactive application of *inter partes* review is a categorical taking under *Lucas*.

The economic impact in this case is so severe that the government action is a categorical taking under *Lucas*, 505 U.S. at 1015. When a "regulation denies all economically beneficial or productive use of land," the regulation is a *per se* taking, regardless of the other *Penn Central* factors. *Id.*; see also *Lingle*, 544 U.S. at 538 ("regulations that completely deprive an owner" of all economic use of property are "*per se* takings").

Though *Lucas* involved real property, the same rule applies to personal property such as patents, at least where the government extinguishes the property right altogether. In that circumstance, the regulation is akin to a direct appropriation because the government has confiscated a property right in its entirety. See *Horne*, 135 S. Ct. at 2427-28 (the law treats "direct

appropriations of real and personal property alike”). Just as the government’s direct appropriation of personal property in *Horne* was a categorical taking, the government’s direct elimination of Celgene’s patent claims—particularly with Celgene lacking any ability to amend its claims in response to the Board’s invalidity decision—was a categorical taking here.

This is not a case where the regulation leaves the property owner with more than a “token interest.” *Palazzolo v. Rhode Island*, 533 U.S. 606, 631 (2001). In *Palazzolo*, for example, the Court rejected a takings argument because the challenged state regulation still permitted the “landowner to build a substantial residence on an 18-acre parcel” of land, even though state law designated most of the parcel as protected wetland. *Id.* Here, by contrast, retroactive *inter partes* review canceled all but one claim of the ’720 patent, leaving Celgene with merely a token interest. And retroactive *inter partes* review canceled the ’501 patent, leaving Celgene with nothing.

B. Retroactive application of *inter partes* review is a regulatory taking under *Penn Central*.

At minimum, the AIA imposes a regulatory taking under *Penn Central*. That case described the governing test as “essentially ad hoc, factual inquiries” centered on three factors: (1) the “extent to which the regulation has interfered with distinct investment-backed expectations,” (2) the “character of the governmental action,” and (3) the “economic impact of the regulation.” 438 U.S. at 124. All three *Penn Central* factors support Celgene here.

Investment-backed expectations. As discussed above, *supra* pp. 4-5, patent holders make substantial investments of resources to develop patentable inventions in return for time-limited exclusionary rights. This Court has warned that changes in patent law must not “disrupt the settled expectations of the inventing community.” *Festo*, 535 U.S. at 739.

With retroactive *inter partes* review, Congress impermissibly—and unilaterally—added a new term to the “carefully crafted” patent bargain after the deal was done. *Bonito Boats*, 489 U.S. at 150. This eviscerated the settled expectations of all patent owners who received patents for their inventions prior to 2011. Before the AIA was enacted, patent owners weighed the cost and the value of investing in innovation, of disclosing their inventions to the public in exchange for exclusive property rights, and of licensing or otherwise putting their inventions to use during the 20-year patent term. The AIA then retroactively and radically changed that cost-benefit analysis.

In short, Congress pulled the rug from innovators who thought they held patent rights that could be defeated only in district court or through the rarely invoked and dubiously constitutional vehicle of reexamination. Those patent rights, it now turns out, are always held at the mercy of the Board—or, as a former Federal Circuit Chief Judge called it, the “patent death squad.”¹⁷ Here, the State has indeed placed too

¹⁷ Ryan Davis, *PTAB’s ‘Death Squad’ Label Not Totally Off-Base, Chief Says*, Law360 (Aug. 14, 2014), <https://www.law360.com/articles/567550/ptab-s-death-squad-label-not-totally-off-base-chief-says>; see also Peter J. Pitts, *Patent Death Squad’ vs. Innovation*, WALL ST. J. (Jun. 10, 2015),

“potent a Hobbesian stick into the Lockean bundle.” *Palazzolo*, 533 U.S. at 627.

The Federal Circuit was wrong to dismiss this concern. It reasoned that *inter partes* review does not “differ from the pre-AIA review mechanisms significantly enough, substantively or procedurally, to effectuate a taking.” Pet. App. 30a. According to the court, patent reexamination has been around for decades, and *inter partes* review makes only minor changes.

This reasoning is not plausible. Of course the AIA made revolutionary changes to post-issuance review. That is exactly what Congress’s wholesale redesign of post-issuance review was designed to do, and that is exactly how the empirical data show it to be working. *See supra* pp.13-14. Congress does not fund a 270-member board of “judges” for nothing.

The Federal Circuit’s reasoning further ignores the synergy of the individual differences between reexamination before the Board and *inter partes* review before a patent examiner. It also ignores the data showing the AIA’s real-world effect on patent cancelation rates. Under the new regime, a patentee’s chance of facing petitions for post-issuance review is higher, as is the chance of losing its claims during the proceeding. *Supra* pp.13-14. The court’s reasoning also vastly understates the broader impact of the new regime. After Congress enacted the AIA, the value of all patents dropped, with sales reports showing that it dropped by two-thirds, costing the economy a trillion dollars. *Supra* p.14.

Nor was the court correct to rely on the general principle that no one has a “vested right in any given mode of procedure.” Pet. App. 37a. The changes at issue here “go[] beyond ‘mere’ procedure to affect substantive entitlement to relief.” *Lindh v. Murphy*, 521 U.S. 320, 327 (1997). This is true for two reasons.

First, the Federal Circuit ignored the most significant substantive change: the right to amend claims. Elimination of the unfettered right to amend—a right the patentee could exercise throughout an *inter partes* reexamination, including in response to the PTO’s invalidity decision—amounts to a substantive change. An amendment alters the substantive boundaries of the patent. And claim amendments are inextricably connected with the substantive standards for patentability because the purpose of claim amendments is to match those standards with the scope of the claim. *Supra* p.10. Congress’s elimination of the right to amend is not fairly distinguishable from a change to “standards of proof and persuasion” that “affect substantive entitlement to relief.” *Lindh*, 521 U.S. at 327.

Second, as a whole, the scheme of *inter partes* review has such extreme consequences on substantive patent rights that it must be viewed as “go[ing] beyond ‘mere’ procedure to affect substantive entitlement to relief.” *Id.* The “Coalition” of hedge-funders chose *inter partes* review rather than *ex parte* reexamination in these cases for good reason. The effect of *inter partes* review is to cancel thousands of patents that would not have been canceled under the old regime. If Congress were to simply declare those patents invalid, no one could resist the conclusion that it was a taking. Congress has achieved the same result here by delegating that responsibility to the Board.

Combined, the changes wrought by the AIA place a patent on different substantive footing than under any previous system of post-issuance review. The result is that the risk of a post hoc determination by the agency canceling the property right is significantly higher after the AIA.

Finally, for its part, the PTO defended retroactive application of its new powers by relying on the remarkable and incorrect proposition that patents are “necessarily provisional” throughout their 20-year term, such that a patent owner “never ha[s] a valid property interest” in its patents because the Board may, someday prior to patent expiration, conclude that its agency erroneously issued them in the first place. PTO Br. 40-41 (No. 18-1167). That is an astonishing view of property ownership—you may only own property unless and until the government decides you may not.

In the correct view, a patent vests as property when it is issued. At that point, the “patent shall be presumed valid.” 35 U.S.C. § 282(a). And the “patent[] shall have the attributes of personal property.” *Id.* § 261. Of course the property right is qualified by compliance with the patent laws in effect at the time the patent issues. *Oil States*, 138 S. Ct. at 1375. But the property right is not qualified by new laws enacted afterward. *McClurg*, 42 U.S. (1 How.) at 206; *see supra* p.23.

Character of the government action. “A ‘taking’ may more readily be found when the interference with property can be characterized as a physical invasion by government, than when interference arises from some public program adjusting the benefits and burdens of economic life to promote the common

good.” *Penn Cent.*, 438 U.S. at 124 (citation omitted). The result of *inter partes* review is much more akin to a physical invasion than to a mere “adjust[ment].” When *inter partes* review ends with cancelation of a patent claim, the result is a total elimination of the property. This is closely analogous to a confiscation of tangible personal property, which is indisputably a taking, even when part of a larger regulatory program. *Horne*, 135 S. Ct. at 2427.

Under the “ad hoc factual” inquiries of *Penn Central*, 438 U.S. at 124, the AIA’s retroactivity is an additional factor showing that *inter partes* review amounts to a taking. A core purpose of the Takings Clause is to safeguard against retrospective legislation concerning property rights. *Landgraf v. USI Film Prods.*, 511 U.S. 244, 266 (1994). Moreover, retroactive legislation “is generally disfavored in the law,” *E. Enters.*, 524 U.S. at 532, “because it can deprive citizens of legitimate expectations and upset settled transactions.” *Gen. Motors Corp. v. Romein*, 503 U.S. 181, 191 (1992). Retroactive application of *inter partes* review thus clashes with the general principle against retroactive legislation and with the core purpose of the Takings Clause.

And the AIA is indeed retroactive. The statute “attaches new legal consequences” or a “new disability” to patents issued before its enactment. *Landgraf*, 511 U.S. at 269-70; *see* 35 U.S.C. § 311 note (applicability to patents issued before enactment). Those new legal consequences consist of invalidating patents through the novel framework of *inter partes* review.

Economic impact. For any patent owner whose patent is invalidated in an *inter partes* review, all economic value of the patent is eliminated. For instance,

here, Celgene has been deprived of the entire value of its '501 patent and of all but a single claim in its '720 patent.

Maybe the government would also have deprived Celgene of its patents through reexamination under the old regime, but that is highly doubtful. Based on the far lower number of reexamination petitions filed, the chances of anyone instituting reexamination against Celgene were much lower. *Supra* p.13-14. And based on the much lower kill rate in reexamination proceedings, the chances of losing all claims in reexamination were exceedingly small, especially because Celgene would have had an unlimited right to amend its claims throughout the entirety of the reexamination proceeding. One must therefore view the economic impact of *inter partes* review on Celgene as the loss of its '501 patent and nearly all of its '720 patent.

In sum, canceling patents through retroactive application of *inter partes* review is a taking of property without compensation. This result is the same under the categorical test applied in *Lucas*, or under the ad hoc factual inquiries applied in *Penn Central*.

III. THIS CASE IS AN IDEAL VEHICLE.

Finally, this case is an ideal vehicle. The Federal Circuit fully addressed the merits of the issue below. It then denied *en banc* review, thereby cementing the ruling into national law. Indeed, the decision here is already dictating the outcomes in other cases, including one with a petition currently pending before this Court. *See, e.g., Collabo Innovations, Inc. v. Sony*

Corp., No. 18-1311, 2019 WL 3545450, at *4 (Fed. Cir. Aug. 5, 2019) (No. 19-601 filed Nov. 4, 2019).¹⁸

Nor can the issue percolate in other courts. Only the Federal Circuit has jurisdiction to review decisions of the Board. In short, this case presents the best opportunity for this Court to resolve the important constitutional issue at stake.

Patlex presents an important lesson about the need for this Court's review at this time. No party sought review of the Federal Circuit's 1985 decision in *Patlex*, and no other appellate court could reach the issue. So the incorrect rule that Congress may retroactively legislate vested patent property rights out of existence just as long as it avoids doing so "in an arbitrary and irrational way," 758 F.2d at 603, has been cemented into national law for 35 years now. The Court should not allow that incorrect approach to fester any longer.

CONCLUSION

The petition for a writ of certiorari should be granted.

¹⁸ See also *Arthrex, Inc. v. Smith & Nephew, Inc.*, 935 F.3d 1319, 1331 (Fed. Cir. 2019); *Enzo Life Scis., Inc. v. Becton, Dickinson & Co.*, No. 18-1232, 2019 WL 3851578, at *7 (Fed. Cir. Aug. 16, 2019) (all citing *Celgene* as dispositive of takings challenges, without further analysis).

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